

REMARKS

Claims 3, 25 and 26 remain in the application and under consideration. Claims 3, 25 and 26 were rejected under 35 USC 102(b) as being anticipated by Anderson et al. Claims 25 and 26 have been amended slightly to define the invention more clearly.

The undersigned attorney and the above-identified inventor thank Examiner Blanco and Primary Examiner Willse for the courtesies extended during the interview on March 9, 2004. Counsel had sent Examiner Blanco a draft Amendment prior to the interview. The proposed Amendment then was discussed at considerable length during the interview. Additionally, a prototype of the invention was displayed during the interview along with samples of introducers that are used to introduce an endovascular sent/graft assembly. Both Examiner Blanco and Primary Examiner Willse indicated that they understood the invention and appreciated the differences between an end-to-end connection without overlap and a substantially end-to-end connection with some overlap as taught, for example by Anderson et al. However, Primary Examiner Willse suggested that the two independent claims be amended further to incorporate functional language that explains the advantages of the claimed invention over the prior art. It was suggested that claims with such functional language would help with a more favorable consideration of the Amendment.

This Amendment differs from the Amendment that was discussed during the interview in that the requested functional language has been incorporated. This new language has support at page 3, lines 7-12 of the specification where the first two objects of the invention are described. Counsel appreciates that this application is under final rejection, and it is not certain to counsel whether these fairly minor amendments would be

considered grounds for refusal of entry of this Amendment. Accordingly, this Amendment After Final Rejection is being submitted concurrently with a Request for Continued Examination and an authorization to charge Deposit Account No. 03-1030 for the required fees associated with an RCE. The remaining sections of these remarks parallel the remarks presented in the draft Amendment and conform to the matters discussed during the interview.

The Office Action referred to FIGS. 9, 10 and 12 of Anderson et al. and concluded that the reference discloses an endovascular sent/graft assembly with stents 56 and 58 each of which has opposite first and second axial ends. The Examiner noted that the Anderson et al. reference also has a graft 52 with first and second ends. The graft of Anderson is disposed to bridge an aneurysm. The Examiner then asserted that the first axial end of the graft is fixedly connected with the second axial end of the stent for achieving a "substantially end-to-end connection" (emphasis added). The Examiner acknowledged that "said end-to-end connection includes overlapping (see FIGS. 9, 10 and 12)." The Examiner then referred to the applicant's earlier assertions regarding the presence or absence of overlapping of the stent and graft in Anderson et al. For this purpose, the Examiner referred to col. 11, lines 11-14 of Anderson et al. which state "at least a portion of stents 56, 58 extend out of graft 52, and if the stents and graft are joined by a butt joint, then substantially all of the stent will extend out of the graft." The Examiner then turned to Merriam-Webster dictionary which defines "butt joint" as "a joint made by fastening the parts together in end-to-end without overlap and often with reinforcement". As a result, the Examiner concluded that the Anderson et al. reference anticipates the invention as previously claimed.

A rejection for anticipation under Section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. In addition, the reference must be enabling. *In re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994). Additionally, a reference must be considered in its entirety and "must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." *In re Spada*, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

The Examiner acknowledges in the last sentence of paragraph 4 of the detailed action that the end-to-end connection taught by Anderson et al. "includes overlapping (see Figures 9, 10 and 12)". The Examiner is basically correct in paragraph 4 of the detailed action. For example, FIGS. 14 and 15 of Anderson et al. show a very substantial overlap of the stent and graft (see section through graft in FIG. 14 and broken line depiction of stent in FIG. 15). However, even the end-to-end connection of FIGS. 8, 9, 10 and 12 include the overlap referred to in the above-quoted section of paragraph 4 of the detailed action.

The section of the Anderson et al. specification at col. 11, lines 11-14 and quoted in paragraph 5 of the detailed action is in a portion of the Anderson specification referring to the FIGS. 8-10 embodiments. It is submitted that a person having ordinary skill in this art would interpret the sentence at col. 11, lines 11-14 as defining the FIGS. 8-10 embodiment described throughout that section of the Anderson et al. specification. More particularly, the "butt joint" referred to in this section of the Anderson et al. specification would be considered by one skilled in the art to identify the embodiment depicted in FIGS. 8-10 where "substantially all of the stent will extend out of the graft" but where a relatively

small portion of the stent and graft overlap as acknowledged in paragraph 4 of the office action. Clearly, Anderson et al. is not "enabling" for any non-overlapping relationship between a stent and a graft, and nothing in the Anderson et al. reference indicates that Anderson et al. "had possession" of that aspect of applicant's invention. Possession of that aspect of applicant's invention would have required Anderson et al. to have at least shown such a connection without overlap. Furthermore, the interpretation asserted in paragraph 5 of the detailed action is inconsistent with Anderson's use of "substantially" in the above-quoted section of the Anderson et al. specification. Counsel and the applicant herein do not dispute that substantially all of the stent of the Anderson et al. "butt joint" extend out of the graft, but clearly part of the stent of the Anderson et al. "butt joint" extends into the graft to achieve the only substantially end-to-end connection disclosed in Anderson et al.

The Examiner's need to rely upon Merriam-Webster to boot strap the brief mention of "butt joint" into a rejection would seem to refute the position that Anderson et al. is anticipatory. The need to transport an interpretation from Merriam-Webster into Anderson et al. seems to support the admission in paragraph 4 of the detailed action that Anderson et al. shows only overlap. Thus, the assertion in paragraph 5 of the detailed action and the reliance upon Merriam-Webster is more in the nature of a Section 103 obviousness rejection where the Examiner asserts that a person skilled in the relevant art would construe "butt joint" in the manner taught by Merriam-Webster, and not in the manner illustrated and described in detail throughout Anderson et al. However, "butt joint", as used by Merriam-Webster is believed to be associated more with carpentry and joining wood and is not a term of art as normally used by those with ordinary skill in the

endovascular stent/graft art. It is submitted that a person having ordinary skill in the endovascular stent/graft art would not turn to the carpentry art for purposes of developing the Anderson et al. stent/graft assembly beyond the clear teaching of Anderson et al., which provides at least some overlap between the stent and the graft.

The end-to-end connection with no overlap, as set forth in the amended claims, may not seem to be significantly different from the small overlap between the stent and graft shown in FIGS. 8-10 of Anderson et al. However, as noted in applicant's earlier response, the difference is very substantial. The size of the introducer used to introduce an endovascular stent/graft assembly into a blood vessel is determined by the maximum cross-sectional dimension along the length of the endovascular stent/graft assembly. That maximum cross-sectional dimension would be determined by the dimensions existing at the overlap.

Surgeons who perform these types of operations refer to the "French size" of the graft, stent or introducer. The French size refers to the outer circumference of the stent or graft in millimeters. An overlapped stent/graft assembly, as shown in Anderson et al., would require an introducer of 20 or 22 French. In contrast, the claimed end-to-end connection of the stent and graft avoids the additional dimensions attributable to the telescoped overlap of Anderson and further avoids the additional dimensions attributable to pleating or other gathering the graft onto the collapsed stent. Hence, the claimed stent/graft assembly can be used with a 12 French introducer. These size, are shown below:



22 French



12 French

The difference between a 12 French introducer and 20 or 22 French introducer is tremendous in terms of the surgical and post-surgical implications. In this regard, the aneurysm is likely to occur in an artery and not a vein. Therefore, the endovascular stent/graft assembly must be introduced into an artery and not a vein. The typical site of introduction is the femoral artery, which is one of the larger arteries in the body. Arterial blood, unlike venous blood, is under tremendous pressure. Thus, an incision into an artery, such as the femoral artery, produces a very significant gushing and pulsating flow of blood. The incision into a major artery for a 20 or 22 French introducer is likely to produce significant bleeding and requires a more complicated closure. In contrast, the opening for a 12 French introducer produces much less bleeding during surgery and the closure is sufficiently simple to permit the surgery to be performed on an outpatient basis. The incision for a 12 French introducer generally can be closed merely with pressure and a dressing, and without sutures. The incision for a 20 or 22 French introducer requires sutures and typically requires a stay in the hospital while the closure is monitored for proper healing. Thus, the claimed invention enables an otherwise complex surgical procedure to be reduced more to the nature of a dentist visit.

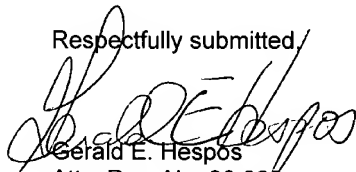
Additionally, the femoral arteries of most women are too narrow for the overlapping endovascular devices shown in Anderson et al. Thus, a woman with an aneurysm typically will require a direct surgical repair at the site of the aneurysm, and a much longer hospital stay. However, the end-to-end connection with no overlap provided by the stent/graft assembly of the subject invention would enable women with an aneurysm to have the aneurysm repaired with an endovascular stent/graft assembly.

Anderson et al. has no suggestion of the structure defined by the amended claim nor the advantages enabled by the subject invention, as set forth above.

Accordingly it is submitted that the invention defined by the amended claim is directed to patentable subject is solicited.

In view of the preceding amendments and remarks, it is submitted that the invention defined by the amended claims herein is patentable over Anderson et al.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "G. E. Hespos", is written over the typed name.

Gerald E. Hespos

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